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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,292	07/10/2003	Lawrence J. DeLucas	704641-2001	2655

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EXAMINER

MOSS, KERI A

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/617,292	Applicant(s) DELUCAS ET AL.	
	Examiner Keri A. Moss	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 9-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/7/05, 8/18/03, 6/22/06</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-8 in the reply filed on November 6, 2006 is acknowledged. The traversal is on the ground(s) that both groups were drawn to technologies for distinguishing between biomolecule crystals and non-biocrystals. This is not found persuasive because the two inventions are classified in two different classes and further because claims 9-24 require the use of two sensors, whereas the method of claims 1-8 does not. These differences demonstrate the different field of search and the burdensome search to the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The Examiner acknowledges receipt of the lengthy information disclosure statement filed December 07, 2005. There is no requirement that applicants explain the materiality of English language references, however the cloaking of a clearly relevant reference in a long list of references may not comply with applicants' duty to disclose, see Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F. Supp. 948, aff'd 479 F. 2d. 1338. There is no duty for the Examiner to consider these references to a greater extent than those ordinarily looked at during a regular search by the Examiner.

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Accordingly, the Examiner has considered these references in the same manner as references encountered during a normal search of Office search files.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Based on the specification, one of ordinary skill in the art would not be apprised of the metes and bounds of what Applicant means by "biomolecule". In the published version of the application, paragraph 49, the specification teaches that non-biomolecule crystals of sugars do not substantially absorb UV. However, one of ordinary skill in the art understands that the compounds considered to be biomolecules include lipids, vitamins, hormones, carbohydrates (such as sugar), disaccharide, nucleic acids, peptides, proteins and prions (see Wikipedia "biomolecule"). Paragraph 49 also conflicts with the teaching that biomolecule DNA absorbs UV, since DNA comprises sugars (see paragraph 51). How does DNA absorb UV while its components do not? Further, if a component molecule of a biomolecular compound does not substantially absorb UV while the biomolecular compound as a whole does absorb UV, what causes the

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biomolecular compound to absorb UV radiation? The specification does not address this question. If DNA, a "biomolecule" according to the specification, is comprised of sugars, a "nonbiomolecule" according to the specification, it is unclear what applicant means by "biomolecule". One of ordinary skill in the art understands a biomolecule to be a chemical compound that naturally occurs in living organisms (See Wikipedia, "biomolecule"). Sugars are considered biomolecules as they occur naturally in living organisms, for example in the DNA helix backbone. If applicant considers sugars to be nonbiomolecules when one of ordinary skill in the art understands that sugars are biomolecules, it is unclear what molecules applicant is referring to when using the term biomolecule.

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides, molecules containing peptides does not reasonably provide enablement for all biomolecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The application teaches a method for distinguishing between biomolecule crystals and non-biomolecule crystals by detecting a change in the quantity or character of electromagnetic radiation. The compounds considered to be biomolecules include lipids, vitamins, hormones, carbohydrates (such as sugar), disaccharide, nucleic acids, peptides, proteins and prions (see Wikipedia "biomolecule"). As demonstrated infra, it is commonly known among those with ordinary skill in the art that proteins absorb UV rays

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to a greater degree than inorganic salts do. Chemical reactions by their nature are inherently unpredictable. Therefore, whether a biomolecule other than those disclosed absorbs electromagnetic radiation of a certain wavelength to a greater degree than other wavelengths is unpredictable. Also unpredictable is the wavelength at which a biomolecule absorbs a certain wavelength of EM radiation to a significant degree. The working example uses only proteins, which are peptide chains. In addition, applicant has expressly limited the types of biomolecules enabled by the disclosure. On page 49, applicant teaches that sugars are considered non-biomolecules. However, as discussed supra, those with ordinary skill in the art understand sugars, i.e. carbohydrates, to be biomolecules. Since applicant teaches that sugars do not substantially absorb UV radiation, sugars are at least one type of biomolecule crystal that are not enabled by applicant's method. It would require undue experimentation to determine whether the undisclosed biomolecule, such as a lipid that does not contain peptides, does in fact absorb electromagnetic radiation differently at one wavelength than another to a significant degree. It would further require undue experimentation for one to use the invention with biomolecules other than proteins because one would have to do experiments to determine the wavelengths at which the biomolecule crystal absorbs radiation differently than it absorbs other wavelengths. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The above analysis demonstrates that the specification does not reasonably provide enablement for all biomolecules.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "biomolecule" in claims 1-8 is used by the claim to mean "compounds such as peptides, molecules containing peptides and nucleic acids but not including sugars", while the accepted meaning is "a chemical compound that naturally occurs in living organisms, including peptides, proteins, carbohydrates, lipids, vitamins, etc." The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Oka et al. (USP 5,214,288). Oka teaches a method for two dimensional measurement of the concentration of crystallized biomolecules, such as proteins and nucleic acids, in a solution. A crystallizing agent, such as salt, is added to the solution prior to detection (column 3 lines 38-48) in a protein/nucleic acid:crystallizing agent volume ratio of 1:5 or 1:1 (column lines 15-29). With a UV wavelength of about 280 nm and 260nm (column 4 lines 10-21), the protein crystals are detected and used to determine the protein concentration (column 2 lines 41-54). The method distinguishes between the crystallizing agent and the protein by detecting the change in the character of the UV radiation (column 7 lines 3-16). Visible light is exposed to the sample in the form of ambient light.

11. Claims 1, 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hassard (USP 6,613,210). Hassard teaches a method of distinguishing proteins and nucleic acids from nonbiomolecules such as sugars by providing UV light at about 230 nm (column 3 lines 21-27; column 4 lines 30-36). Visible radiation is provided in the form of ambient light.

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Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka or Hassard, *supra*, in view of Cima (US Pub 2002/0048610). Oka and Hassard do not expressly teach distinguishing between biomolecules and nonbiomolecules using two

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types of electromagnetic radiation that varies in the polarization. Cima teaches that images created using different light polarization can be used to identify crystals (paragraph 307). Additionally, polarized light analysis can be used to discern different polymorphs (paragraph 308). Cima teaches that the disclosed methods are practical, cost-effective and rapid methods for screening samples (paragraph 32). Therefore, it would have been obvious for one of ordinary skill in the art to modify the methods of Oka or Hassard by using polarized light to identify and distinguish between crystals in order to make a more cost-effective and faster method.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keri A. Moss
Examiner
Art Unit 1743

KAM 1/18/07



LYLE A. ALEXANDER
PRIMARY EXAMINER